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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/009,607	11/21/2001	Masahiro Imoto	1830/50520	4194

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EXAMINER	
RAO, DEEPAK R	

ART UNIT	PAPER NUMBER
1624	6

DATE MAILED: 07/08/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
10/009,607	Imoto et al.
Examiner	**Art Unit**
Deepak Rao	1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *May 9, 2003*.

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-34* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-34* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☒ None of:

1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 3
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Claims 1-34 are pending in this application.

Election/Restriction

Applicant's election with traverse of Group III, drawn to compounds of formula (I) wherein -Y-X- is $-CH_2-CH_2-NH-$ or $-C(R^7)=C(R^8)-N=$ in Paper No. 5 is acknowledged. The traversal is on the ground(s) that the restriction is improper. This is not found persuasive because the compounds of instant claims are drawn to a plurality of compounds all of which are classified separately in various class/subclasses (involving review of thousands of patent documents) and require separate **burdensome** searches in the literature and computer databases. Compounds containing such diverse groups do not form a single inventive concept within the meaning of 35 U.S.C. 121 because a reference that anticipates or renders obvious one of the groups would not necessarily render obvious another group and applicants have not clearly stated on the record that this is not the case. Applicant's arguments referring *In re Weber* are fully considered but they were not found to be persuasive. The claimed compounds contain plural diverse substituted nitrogen heterocyclic rings/ring systems as can be seen from the structural formula (I) having variables X, Y, A, B^1 and B^2 and the definitions of variables, which is clear evidence to show that each of the inventions of the Groups is distinct and independent.

The instant claims do encompass separate and distinct inventions that have acquired separate status in the art, will support separate patents, and will require different fields of search

for the respective inventions. Further, the instant application is a national stage application and therefore, must comply with the PCT Rule 13 according to which "A group of inventions is considered linked to form a single general inventive concept where there is a technical relationship among the inventions that involves at least one common or corresponding special technical feature", see MPEP § 1893.03(d). Also, the instant claims do not meet the 'unity of invention' requirements as defined in Administrative Instructions under the PCT. The relevant information from MPEP is provided below for convenience.

ANNEX B
UNITY OF INVENTION
PART 1
INSTRUCTIONS CONCERNING UNITY OF INVENTION

Markush Practice. The situation involving the so-called Markush practice wherein a single claim defines alternatives (chemical or non-chemical) is also governed by Rule 13.2 . In this special situation, the requirement of a technical interrelationship and the same or corresponding special technical features as defined in Rule 13.2 , shall be considered to be met when the alternatives are of a similar nature.

(i) When the Markush grouping is for alternatives of chemical compounds, they shall be regarded as being of a similar nature where the following criteria are fulfilled:

(A) all alternatives have a common property or activity, and

(B) (1) a common structure is present, i.e., **a significant structural element is shared by all of the alternatives**, or

(B) (2) in cases where the common structure cannot be the unifying criteria, all alternatives belong to a recognized class of chemical compounds in the art to which the invention pertains.

(ii) In paragraph (f)(i)(B)(1), above, the words significant structural element is shared by all of the alternatives refer to cases where the compounds share a common chemical structure which occupies a large portion of their structures, or in case the compounds have in common only a small portion of their structures, the commonly shared structure constitutes a structurally distinctive portion in view of existing prior art. The structural element may be a single component or a combination of individual components linked together.

(iii) In paragraph (f)(i)(B)(2), above, the words recognized class of chemical compounds mean that there is an expectation from the knowledge in the art that members of the class will behave in the same way in the context of the claimed invention. In other words, each member could be substituted one for the other, with the expectation that the same intended result would be achieved.

(iv) The fact that the alternatives of a Markush grouping can be differently classified shall not, taken alone, be considered to be justification for a finding of a lack of unity of invention.

(v) When dealing with alternatives, if it can be shown that at least one Markush alternative is not novel over the prior art, the question of unity of invention shall be reconsidered by the examiner. Reconsideration does not necessarily imply that an objection of lack of unity shall be raised.

As can be seen from above, Unity of invention is deemed to be present if both conditions (A) and (B) are met. A review of the structural formula (I) shows that there is no 'significant structural element' common to all alternatives, i.e., the heterocyclic ring forms different ring systems based on the definition of -Y-X-. Since there are variations among the members of the heterocyclic rings, each separate combination of -Y-X- ring members establishes a different "significant structural element" upon which a reasonable search and examination may take place. Further, these alternatives do not belong to a recognized class of compounds. Therefore, the instantly claimed generic structure does **not** meet the criteria of (B)(1) and thus, lacks unity with any of the other combinations. The generic structure does **not** satisfy the criteria of (B)(2) because all of the alternatives do not belong to a recognized class of chemical compounds in the art.

Applicant's argument that the compounds of Group III are homologs of Group II, etc. is fully considered, however, diazines vs. diazoles are not art recognized equivalents. They are patentably distinct such that if a compound of Group III consisting of imidazole were anticipated, the applicants would not acquiesce in rejection of any of the other groups there over or vice-versa.

The requirement is still deemed proper and is therefore made FINAL.

Applicant's election of the species of Compound No. 7 (page 26, Table 2) is acknowledged. The species represents a compound of formula (I) wherein:

-Y-X- is -CH=CH-N=;

n is 2;

B^1 and B^2 are H; and

A is 6-chloro-pyrid-3-yl.

The guidelines in MPEP § 803.02 provide that upon examination if prior art is found for the elected species, the examination will be limited to the elected species.

Content of MPEP § 803.02 is provided here for convenience:

> As an example, in the case of an application with a Markush-type claim drawn to the compound C-R, wherein R is a radical selected from the group consisting of A, B, C, D and E, the examiner may require a provisional election of a single species, CA, CB, CC, CD or CE. The Markush-type claim would then be examined fully with respect to the elected species and any species considered to be clearly unpatentable over the elected species. If on examination the elected species is found to be anticipated or rendered obvious by prior art, the Markush-type claim and claims to the elected species shall be rejected, and claims to the non-elected species would be held withdrawn from further consideration. As in the prevailing practice, **a second action on the merits on the elected claims would be final.**
> On the other hand, should no prior art be found that anticipates or renders obvious the elected species, the search of the Markush-type claim will be extended. If prior art is then found that anticipates or renders obvious the Markush-type claim with respect to a nonelected species, the Markush-type claim shall be rejected and claims to the nonelected species held withdrawn from further consideration. **The prior art search, however, will not be extended unnecessarily to cover all nonelected species.** Should applicant, in response to this rejection of the Markush-type claim, overcome the rejection, as by amending the Markush-type claim to exclude the species anticipated or rendered obvious by the prior art, the amended Markush-type claim will be reexamined. The prior art search will be extended to the extent necessary to determine patentability of the Markush-type claim. In the event prior art is found during the reexamination that anticipates or renders obvious the amended Markush-type claim, the claim will be rejected and the action made final. Amendments submitted after the final rejection further restricting the scope of the claim may be denied entry.

The elected species identically was not found in the prior art search and the search was expanded to the subgenus of formula (I) wherein -Y-X-, n, B^1 and B^2 are as indicated above and A is optionally substituted alkyl and art was found. As per the guidelines of MPEP § 803.02, the

Markush-type claims were examined to the extent of the searched subgenus. The non elected species in claim 2 (i.e., compounds other than imidazoles) and the generic subject matter (i.e., all other definitions of -Y-X-, B^1 and B^2) drawn to the non elected species from claims 1 and 3-34 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to non-elected inventions.

Priority

Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Japan on April 21, 2000. It is noted, however, that a certified copy of the priority document is not present in the national stage application. Further, receipt of the priority document has **not** been acknowledged by the International Bureau Designated Office (see Form PCT/DO/EO/903 wherein there is **no** indication that priority document has been received). If applicant has not forwarded a certified copy of the priority application in time for the International Bureau to forward it to the U.S. Designated Office with the copy of the international application, then applicant will have to provide a certified copy of the priority document during the national stage to fulfill the requirement of 37 CFR 1.55(a)(2). See MPEP § 1893.03(c).

Claim Rejections - 35 U.S.C. § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to

which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 5-21 and 26-33 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the treatment of anxiety, does not reasonably provide enablement for **preventing** or treating of all types of cerebral circulation diseases, neurodegenerative diseases, etc. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

In evaluating the enablement question, several factors are to be considered. Note *In re Wands*, 8 USPQ2d 1400 and *Ex parte Forman*, 230 USPQ 546. The factors include: 1) The nature of the invention, 2) the state of the prior art, 3) the predictability or lack thereof in the art, 4) the amount of direction or guidance present, 5) the presence or absence of working examples, 6) the breadth of the claims, and 7) the quantity of experimentation needed.

The scope of the method claims is not adequately enabled solely based on the activity related to $\alpha 4\beta 2$ nicotinic acetylcholine receptor activity provided in the specification. The claim language includes diseases that are known and those that are yet to be discovered, for which there is no enablement. First, the instant claims cover 'diseases' that are known to exist and those that may be discovered in the future, for which there is no enablement provided. The use disclosed in the specification is as pharmaceutical therapeutic agents having affinity for $\alpha 4\beta 2$ nicotinic acetylcholine receptors, useful to treat a laundry list of diseases, which include neurodegenerative diseases, inflammatory intestinal diseases, etc. Test assays and procedures are provided in the

specification at pages 32-35, wherein the *Ki* data for some of the compounds of the invention is provided in Table 8, however, there is nothing in the disclosure regarding how this data correlates to the treatment of the diverse disorders of the instant claims. The disorders encompassed by the instant claims include neurodegenerative diseases, etc., some of which have been proven to be extremely difficult to treat. A state of the art reference, Levin et al. (AD in IDS) expresses that there are many unanswered questions regarding 'the relationship of nicotinic involvement in cognitive function to nicotinic involvement in other types of function', see page 226, col. 2. Also, Holladay et al. (AU in IDS) remarks that "The possible contributions of presently unknown subunits and the existence of more than one nAChR subtype in the same tissue continues to present challenges..." thereby providing the complexities involved in pharmacological responses of nAChRs. Further, there is no reasonable basis for assuming that the myriad of compounds embraced by the claims will all share the same physiological properties since they are so structurally dissimilar as to be chemically non-equivalent and there is no basis in the prior art for assuming the same. Note *In re Surrey*, 151 USPQ 724 regarding sufficiency of disclosure for a Markush group.

Further, the term neurodegenerative diseases covers diverse disorders such as Alzheimer's disease, dementia, hereditary cerebellar ataxias, paraplegias, syringomyelia, phakomatoses, and much more. In fact, Layzer, Cecil Textbook of Medicine (article enclosed), states that "some degenerative diseases are difficult to classify because they involve multiple anatomic locations" (see page 2050). For example, Alzheimer's disease has traditionally been

very difficult or impossible to prevent or even to treat effectively with chemotherapeutic agents. See e.g., the Cecil Textbook of Medicine, 20th edition (1996), Vol. 2, wherein it is stated that "[t]here is no cure for Alzheimer's disease; and no drug tried so far can alter the progress of the disease." (pg. 1994).

The instant claims are drawn to 'A method of **preventing** or treating....' several diseases, and therefore, the instant claim language embraces disorders not only for the treatment, but for "prevention" which is not remotely enabled. Based on the affinity for $\alpha 4\beta 2$ nicotinic acetylcholine receptors, the instant compounds are disclosed to be useful in the "prevention" of neurodegenerative diseases, cerebral circulation diseases, etc., for which applicants provide no competent evidence. "To prevent" actually means *to anticipate* or *counter in advance, to keep from happening etc.* (as per Websters II Dictionary) and therefore it is not understood how one skilled in the art can reasonably establish the basis and the type of subject to which the instant compounds can be administered in order to have the 'preventive' effect. It is inconceivable from the test data of a small number of representative compounds can be correlated to the 'method of **preventing** or treating' of the various claimed disorders, such that the claimed compounds can not only treat but also "prevent" a myriad of diseases associated with the stated activity. Further, there is no evidence on record which demonstrates that the screening test relied upon is recognized in the art as being reasonably predictive of success in any of the contemplated areas of 'prevention'. Such a reasonable correlation is necessary to demonstrate such utilities. See *Ex parte Stevens*, 16 USPQ 2d 1379 (BPAI 1990); *Ex parte Busse et al.*, 1 USPQ 2d 1908 (BPAI

1986) (the evidence must be accepted as "showing" such utility, and not "warranting further study"). Furthermore, there is no evidence of record which would enable the skilled artisan in the identification of the people who have the potential of becoming afflicted with the disorders encompassed by the instant claims.

Part of the difficulty of developing drugs effective for **preventing** of neurodegenerative diseases, etc. lies in the lack of understanding as to why people come down with these disorders and the numerous causes of these disorders. See Maelicke et al. (AT in IDS) stated in their reference: "In spite of the existence of several theories regarding the pathogenesis of AD, the molecular causes of the condition are still unknown", see page 54. Lin et al. (AM in IDS) listed several **obstacles** in drug development and expressed regarding the therapeutic potential of nAChRs, "Although several of these compounds have entered clinical evaluation, none has convincingly demonstrated clinical efficacy for its targeted disease state", see page 1009. Also, Nordberg et a. (sheet 2, AI in IDS) concluded that "Further knowledge about the functional activity of the cholinergic receptors and their role in regulation of transmitter release and signal transduction will be important for the development of putative therapeutic agents in dementia disorders", see page 110. Sandborn et al. (AH in IDS) also expressed 'the need for additional studies to determine the efficacy of the nicotinic therapy for treatment of intestinal inflammation', see page 371. Kihara et al. (AG in IDS) also indicate that 'nicotinic receptors show additional complexities, with ligand binding' and conclude with 'speculative' remarks that they "may have effects that counter the progress of AD".

Thus, factors such as "sufficient working examples", "the level of skill in the art" and "predictability", etc. have been demonstrated to be sufficiently lacking in the use of the invention. In view of the breadth of the claim, the chemical nature of the invention, the unpredictability of ligand-receptor interactions in general, and the lack of working examples regarding the activity of the claimed compounds, one having ordinary skill in the art would have to undergo an undue amount of experimentation to use the invention commensurate in scope with the claims.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

1. Claim 1 contains a plural in the preamble, i.e., "Heterocyclic **compounds**" which appears to be drawn to a mixture of compounds. Replacing the phrase with --A compound -- is suggested. Also, in the last line the recitation of "**salts**" be replaced by -- salt --. Claim 34 also contains the plural term "**Compounds...**" in line 1 which should be replaced with -- The compound --.

2. Claim 2 recites "The following compounds...." in line 1 wherein the plural recitation is not proper acceptable Markush language. Replacing lines 1-2 with -- A compound represented by formula (I) according to claim 1 selected from: -- is suggested.

3. Claim 3 is drawn to a composition "comprising **the** compound..." which appears to be in better form if recited as -- comprising a compound --. Further, a composition generally should contain a carrier or an excipient and the instant claim only recites "the compound" whereby the claim could almost be interpreted as a compound claim. The recitation of 'a carrier or excipient' in addition to the compound is suggested. If applicant amends claim 3 as suggested, then claim 22 that depends from claim 3 should be amended appropriately.

4. In claim 8, the recitation "for protecting the brain" is not understood. It is not clear what is intended by this language. The same appears in claim 17 also.

Claims not particularly addressed above are included because they do not further resolve the above issues.

Claim Rejections - 35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1. Claims 1, 3-9, 14-18, 22-25 and 34 are rejected under 35 U.S.C. 102(a) as being anticipated by Asaka et al., WO 01/10878 (published February 15, 2001). The instantly claimed compounds read on the reference disclosed compound, see the compound (RN 325491-40-5) in the corresponding CAPLUS abstract (134:163283) enclosed herewith. The intended use recitation in the preamble of the composition or medicament claims is not given any patentable weight.

2. Claims 1, 3-9, 14-18, 22-25 and 34 are rejected under 35 U.S.C. 102(e) as being anticipated by Taveras et al., U.S. Patent No. 6,372,747* (effective filing date December 18, 1998). The instantly claimed compounds read on the reference disclosed compound, see the compounds of preparative examples 53-55 and Examples 103 and 105. The intended use recitation in the preamble of the composition or medicament claims is not given any patentable weight. (**Only relevant pages of the patent enclosed*).

3. Claims 1, 3-9, 14-18, 22-25 and 34 are rejected under 35 U.S.C. 102(b) as being anticipated by Dimaio et al., Chem. Abstract 130:4092. The instantly claimed compounds read on the reference disclosed compound, see the compounds (e.g., RN 215782-93-7, etc.) in the

corresponding CAPLUS computer search report enclosed herewith. The intended use recitation in the preamble of the composition or medicament claims is not given any patentable weight.

4. Claims 1, 3-9, 14-18, 22-25 and 34 are rejected under 35 U.S.C. 102(b) as being anticipated by Ulhaq et al., Chem. Abstract 126:246419. The instantly claimed compounds read on the reference disclosed compound, see the compound (RN 188634-03-9) in the corresponding CAPLUS computer search report enclosed herewith. The intended use recitation in the preamble of the composition or medicament claims is not given any patentable weight.

5. Claims 1, 3-9, 14-18, 22-25 and 34 are rejected under 35 U.S.C. 102(b) as being anticipated by Ulhaq et al., Chem. Abstract 126:139500. The instantly claimed compounds read on the reference disclosed compound, see the compounds (RN 186765-59-3) in the corresponding CAPLUS computer search report enclosed herewith. The intended use recitation in the preamble of the composition or medicament claims is not given any patentable weight.

6. Claims 1, 3-9, 14-18, 22-25 and 34 are rejected under 35 U.S.C. 102(b) as being anticipated by Ulhaq et al., Chem. Abstract 125:25771. The instantly claimed compounds read on the reference disclosed compound, see the compound (RN 177906-16-0) in the corresponding CAPLUS computer search report enclosed herewith. The intended use recitation in the preamble of the composition or medicament claims is not given any patentable weight.

7. Claims 1, 3-9, 14-18, 22-25 and 34 are rejected under 35 U.S.C. 102(b) as being anticipated by Boehm et al., Chem. Abstract 120:54763. The instantly claimed compounds read on the reference disclosed compound, see the compound (RN 151830-84-1) in the corresponding

CAPLUS computer search report enclosed herewith. The intended use recitation in the preamble of the composition or medicament claims is not given any patentable weight.

8. Claims 1, 3-9, 14-18, 22-25 and 34 are rejected under 35 U.S.C. 102(b) as being anticipated by Wei et al., U.S. Patent No. 4,431,653 The instantly claimed compounds read on the reference disclosed compound, see the compound of Example 41, etc. The intended use recitation in the preamble of the composition or medicament claims is not given any patentable weight.

Note: a) Applicant cannot rely upon the foreign priority papers to overcome the rejection under 35 U.S.C. 102(a) above because a certified copy and translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

b) Numerous references were found that read on the instantly claimed compounds of formula (I) wherein -Y-X-, n, B^1 and B^2 are as defined for the elected species and A is a optionally substituted alkyl; the above are a representative sample.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-34 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-16 of copending Application No. 09/933,717 (the corresponding PGPub No. 2002/0028809 is relied upon for the claimed subject matter). Although the conflicting claims are not identical, they are not patentably distinct from each other because the instantly claimed compounds are structural homologs of the reference compounds. The reference claims are drawn to compounds of formula (I) wherein -Y-X- is -CH=C(R^8)-N= and further, the species disclosed in claim 2: 2-amino-1(6-chloro-3-pyridyl)methyl-4-methylimidazole. The reference compounds have a -CH_2-A group attached to the ring nitrogen as compared to the instant claims wherein -CH_2-C(B^1)(B^2)-A is attached to the ring nitrogen wherein B^1 and B^2 are H. The instant compounds differ by a -CH_2- group from the reference compounds and are therefore, structural homologs of the reference compounds. The reference compounds are taught to be useful as pharmaceutical therapeutic agents, see claims 2-8. It would have been obvious to one having ordinary skill in the art at the time of the invention to modify the reference compounds to prepare the next homolog. One having ordinary skill in the art would have been motivated to prepare the instantly claimed

compounds because such structurally homologous compounds are expected to possess similar properties.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Duplicate Claims

Applicant is advised that should claim 3 be found allowable, claims 4-9 and 14-18 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). Claim 4 does not contain a limitation that further limits the composition of claim 3. Claims 5-9 and 14-18 recite an intended use of the composition or medicament without setting forth any positive steps or limitations and accordingly, they are substantial duplicates of claims 3 or 4 respectively wherein claim 4 is a duplicate of claim 3.

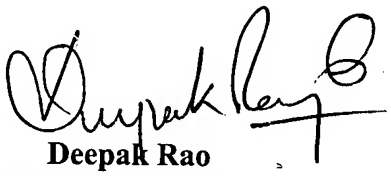
Receipt is acknowledged of the Information Disclosure Statement filed on December 11, 2001 and a copy is enclosed herewith.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deepak Rao whose telephone number is (703) 305-1879. The examiner can normally be reached on Tuesday-Friday from 6:30am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Mukund Shah, can be reached on (703) 308-4716. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.



Deepak Rao
Primary Examiner
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